REMARKS

The Non-Final Office Action of June 20, 2005 has been reviewed, and the comments therein were carefully considered. Claims 1-9, 45 and 46 are pending in the instant application. Claim 1 has been amended in this paper. No new matter has been introduced into the application.

Claims 1-2, 8-9, and 45 stand rejected under 35 USC §102(b) as being anticipated by Kobayashi, U.S. Patent No. 4,469,481.

Kobayashi discloses an apparatus for infusing liquid medication into a living body with a memory for storing infusion patterns in doses commensurate with changes in patient activity. (Col. 2, lines 16-19). More specifically, the drug infusion patterns include a basic pattern based on factors such as the patient's condition, age, sex, and activity (col. 8, lines 40-43) and meal patterns for breakfast, lunch, and supper (col. 8, lines 52-58). The physician is the exclusive operator of the writing device to program the patient's drug infusion patterns. (Col. 19, lines 44-48).

With regard to amended claim 1, Kobayashi does not disclose, teach, or suggest "creating at least one personalized drug therapy program by the patient from the modified at least two preset clinician drug therapy programs, the at least one personalized drug therapy program based on patient activity." In Kobayashi, the patient is only allowed to select when to begin a preset program, and "the patient cannot rewrite the data in the memory of the apparatus either accidentally or intentionally." (Col.19, lines 29-31).

In contrast, Applicant's claimed invention "allows a patient to . . . modify the stored therapy programs to accommodate his/her particular lifestyle, thereby creating and storing personalized therapy programs." (Specification on Page 5, Paragraph 15 (Emphasis added)). Support for the claimed feature of "creating at least one personalized drug therapy program by the patient" may be found in the Specification on Pages 12-13, Paragraphs 48-49, which states:

> The patient could then scroll through the Menu . . . and select the particular [preset clinician therapy programs] PCTP 170 that he/she wishes to access in order to create at least one personalized therapy program. . . . [T]he patient can then review and modify the preset clinician therapy settings (PCTS) . . . that correspond to the accessed PCTP 170. The patient may then select and optimize a PCTS 180 as necessary or desired . . . .

> The patient can then make changes as desired for any of the other remaining PCTS 180 of the accessed PCTP 170 as necessary to create a personalized therapy program 190. Once the patient has created a personalized therapy program 190, a Save function can be selected. . . . For example, the user could label the just created personalized therapy program 190 a "Sleep" program. The patient would then select a Store function and . . . store the personalized therapy program in the INS memory 100.

Therefore, for at least this reason, it is respectfully submitted that claim 1 is patently distinct over Kobayashi. Dependent claims 2, 8-9, and 45 which ultimately depend from independent claim 1 are allowable for at least the same reason as independent claim 1.

Claims 1-2, 6-7, 9, 45, and 46 stand rejected under 35 USC §102(b) as being anticipated by Fischell, WO 84/03218.

Fischell discloses an implantable programmable infusion pump for infusing medication in accordance with programmable prescription parameters and dosage limits. (Page 2, lines 24-27). The device consists of a medical programming unit (MPU) and a patient programming unit (PPU). (Page 3, lines 10-12). The MPU allows a physician to program basal and supplemental prescription schedules and dosage limits based on an individual patient's physiology. (Page 3, lines 14-17; page 5, lines 16-18). The PPU allows a patient to self-medicate (page 3, lines 12-14), but is limited because "a patient can merely choose to deliver a full or half basal rate, select one of the pre-programmed supplemental prescription schedules, inhibit pump activity, or countermand previous directives." (Page 3, lines 20-25).

With regard to claim 1, Fischell does not disclose, teach, or suggest the creation of a personalized drug therapy program "based on patient activity." (Emphasis added). Fischell is concerned with allowing a patient to select pre-programmed prescription schedules and to choose either a half or full basal rate. Although the dosage limits are based on a particular patient's physiology, they are not based on patient activity.

Support for the claimed feature of "at least one personalized drug therapy program based on patient activity" may be found in the Specification on Page 13, Paragraph 49, which states:

> Once the patient has created a personalized therapy program 190, a Save function can be selected. . . . For example, the user could label the just created personalized therapy program 190 a "Sleep" program. . . . The patient could repeat the above steps to create other personalized therapy programs 190, for example programs such as "Running", "Eating", "Sitting", "Exercising" and others.

As specified above, the creation of personalized therapy programs by patients may be based on a patient's particular activity at a specified moment in time. Such patient activities may include sleeping, running, eating, sitting, or exercising. Fischell does not disclose, teach, or suggest at least this claimed feature.

In addition, like Kobayashi, Fischell does not disclose, teach, or suggest "creating at least one personalized drug therapy program by the patient from the modified at least two preset clinician drug therapy program, the at least one personalized drug therapy program based on patient activity." In Fischell, "[t]he PPU [Patient Programming Unit] can be used by the patient to: (1) request delivery of one of eight supplemental prescription schedules which were pre-programmed by the physician; (2) select half or full basal rate delivery of the pre-programmed basal prescription schedule; (3) inhibit pump operation for 1-hour periods; and (4) countermand the current medication directive." (Page 11, lines 23-30). None of these four patient options allows the patient to create and store a personalized drug therapy program like Applicant's claimed invention.

Therefore, for at least these reasons, it is respectfully submitted that claim 1 is patently distinct over Fischell. Dependent claims 2, 6-7, 9, 45, and 46 which ultimately depend from independent claim 1 are allowable for at least the same reasons as independent claim 1.

Claims 3-5 stand rejected under 35 USC §102(b) as being anticipated by, or in the alternative, under 35 USC §103(a) as obvious over Fischell, WO 84/03218, in view of the teachings of Kobayashi, U.S. Patent No. 4,469,481.

For the reasons discussed above, dependent claims 3-5 which ultimately depend from independent claim 1 are allowable for at least the same reasons as independent claim 1.

Claims 1-9 and 45-46 stand rejected under 35 USC §103(a) as obvious over Ford, U.S. Patent No. 5,681,285, in view of Franetzki, U.S. Patent No. 4,282,872.

Ford discloses a drug library containing a plurality of drug entries for use in a syringe pump. A standard drug library may be customized with additional drug entries through use of a personal computer (PC). (Col. 11, lines 30-33). The customized drug library containing the supplementary drug entries may be downloaded into a syringe pump and utilized to administer selected therapeutics. (Col. 11, lines 33-38). Ford discloses the customization of a standard drug

library similar to the customization of a standard database. The drug entries included in the drug library describe requirements for proper administration of specific drugs. For example, when the physician puts a new drug in the pump, the physician can access a pre-set program with appropriate infusion characteristics for that drug and load that program into the pump. Once the physician selects the program, it remains constant regardless of patient activity.

Franetzki discloses a pre-programmable control device that transmits programs for a microdosing unit, which infuses liquids into a patient's body at a rate determined by the control program. (Abstract). The control device is programmed by the patient's physician according to the patient's characteristics. (Col. 6, lines 54-56). The patient can access the programs and select the desired liquid amount within a range of allowable amounts. (Col. 6, lines 4[illegible]-44). Franetzki enables a diabetes patient to select the amount of insulin required after a meal depending on the number of "bread units" the patient consumed with his/her meal. (Col. 2. lines 14-21).

With regard to claim 1, neither Ford nor Franetzki disclose, teach, or suggest a personalized drug therapy program "based on patient activity." (Emphasis added). Ford is concerned with creation of a drug library containing drug entries having infusion characteristics for particular drugs for use in a syringe pump, regardless of who the patient is or what activity the patient is engaging in. Similarly, in Franetzki the control programs do not correspond to patient activity.

Support for the claimed feature of "at least one personalized drug therapy program based on patient activity" may be found in the Specification on Page 13, Paragraph 49, which states:

> Once the patient has created a personalized therapy program 190, a Save function can be selected. . . . For example, the user could label the just created personalized therapy program 190 a "Sleep" program. . . . The patient could repeat the above steps to create other personalized therapy programs 190, for example programs such as "Running", "Eating", "Sitting", "Exercising" and others.

As specified above, the creation of personalized therapy programs by patients may be based on a patient's particular activity at a specified moment in time. Such patient activities may include sleeping, running, eating, sitting, or exercising. Neither Ford nor Franetzki discloses, teaches, or suggests at least this claimed feature.

In addition, neither patent discloses, teaches, or suggests "creating at least one personalized drug therapy program by the patient from the modified at least one preset clinician

drug therapy program, the at least one personalized drug therapy program based on patient activity." Ford is concerned with allowing a physician to select infusion characteristics for a particular drug. Not only is the physician unable to create programs based on patient activity, but also the patient cannot create and store programs based on his/her activity. Similarly, in Franetzki, the patient can enter the number of "bread units" consumed with his/her meal but cannot create and store drug therapy programs.

Therefore, for at least these reasons, it is respectfully submitted that claim 1 is not obvious over Ford in view of Franetzki. Dependent claims 2-9, 45, and 46 which ultimately depend from independent claim 1 are allowable for at least these same reasons as independent claim 1.

Claims 1-7, 9, 45, and 46 stand rejected under 35 USC §103(a) as obvious over Snell, U.S. Patent No. 5,456,691, in view of Kobayashi, U.S. Patent No. 4,469,481, or vice versa.

Snell discloses a programmer in which a control program for an implantable medical device is constructed from program modules that are selected by a physician. (Abstract). The modules may be individually loaded into the implantable medical device or may be combined into a single program, without necessitating an increase in the memory capacity of the implantable device. (Col. 2, lines 7-10). In Snell, a physician selects the software or functions (e.g., cardioversion or defibrillation) that the patient is expected to require. If the software or function is not loaded, the device will be incapable of performing the function.

With regard to claim 1, neither Snell nor Kobayshi discloses, teaches, or suggests "creating at least one personalized drug therapy program by the patient from the modified at least two preset clinician drug therapy programs, the at least one personalized drug therapy program based on patient activity." In Snell, only a physician or trained specialist can construct control programs from program modules. The patient is not allowed to create or store any programs based on patient activity. As mentioned above, in Kobayashi, the patient is only allowed to select when to begin a preset program, and "the patient cannot rewrite the data in the memory of the apparatus either accidentally or intentionally." (Col.19, lines 29-31).

In contrast, applicant's claimed invention "allows a patient to . . . modify the stored therapy programs to accommodate his/her particular lifestyle, thereby creating and storing personalized therapy programs." (Specification on Page 5, Paragraph 15 (emphasis added)).

Therefore, for at least these reasons, it is respectfully submitted that claim 1 is patentable over Snell in view of Kobayashi. Dependent claims 2-7, 9, 45, and 46 which ultimately depends from claim 1 are allowable for at least the same reason as independent claim 1.

Claim 8 stands rejected under 35 USC § 103(a) as obvious over Snell, U.S. Patent No. 5,456,691, in view of Kobayashi, U.S. Patent No. 4,469,481, as applied to claims 1-7, 9, 45-46 above, and further in view of Franetzki, U.S. Patent No. 4,282,872.

For the reasons discussed above, dependent claim 8 which ultimately depends from independent claim 1 is allowable for at least the same reasons as independent claim 1.

Applicants therefore respectfully request reconsideration of the pending claims and a finding of their allowability. Please feel free to contact the undersigned should any questions arise with respect to this case that may be addressed by telephone.

Respectfully submitted,

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